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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,851	01/14/2004	Darin G. Schaeffer	8627-368 (DN-1484)	3412

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Chicago, IL 60610

EXAMINER

NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/756,851	Applicant(s) SCHAEFFER ET AL.	
	Examiner Timothy J. Neal	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1, 21, and 22 are objected to because of the following informalities: the phrase "though a wall thereof" seems to be inappropriate. The Examiner has assumed the word "though" should be "through". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-9, 11, 16, 22, 25-30, 32, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephens (US 6,224,586).

Stephens discloses:

1. A stent introducer comprising: a sheath (Item 100) made from a flexible plastic material (Col 2 Line 50), said sheath comprising an outer surface and an inner surface (Item 100), said sheath further having a slot extending though a wall thereof and extending along an entire length of said sheath (Item 104), wherein said sheath is adapted to be inserted through a hemostatic valve, said outer surface thereby engaging and opening said hemostatic valve and said inner surface providing an open

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passageway through which a stented catheter is passed to minimize contact between a stent thereon and said hemostatic valve (the Examiner considers the "adapted to" phrase and subsequent language to be functional language and that the reference need not include a valve; the Examiner considers the reference capable of being inserted through a hemostatic valve).

4. The stent introducer according to claim 1, wherein said inner surface of said sheath forms a substantially round cross-section in a free state (Fig 2).
5. The stent introducer according to claim 1, wherein said inner surface of said sheath forms two substantially half-round cross-sections in a free state, said two half-round cross-sections being connected to each other at one side and said two half-round cross-sections defining said slot at another side, said slot being open in said free state (Fig 1).
6. The stent introducer according to claim 1, wherein said sheath comprises a hinge connecting two adjacent portions of said sheath together (Fig 2 Item 112).
7. The stent introducer according to claim 6, wherein said hinge comprises a section of said sheath formed from a thinner cross-section of said flexible plastic material than said two adjacent portions (Fig 2 Item 112).

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8. The stent introducer according to claim 1, wherein a width of said slot is less than a diameter of said stented catheter (Fig 2).

9. The stent introducer according to claim 1, wherein a width of said slot is less than fifty percent of a diameter of said stented catheter (Fig 1).

11. The stent introducer according to claim 1, wherein said sheath comprises a hinge connecting two adjacent portions of said sheath together and a width of said slot is greater than a diameter of said stented catheter (Fig 2 Item 112, the slot will be greater than the width of the catheter so the catheter may be pressed into the slot).

16. The stent introducer according to claim 1, wherein said inner surface of said sheath forms two substantially half-round cross-sections in a free state, said two half-round cross-sections being connected to each other at one side and said two half-round cross-sections defining said slot at another side, said slot being open in said free state (Fig 1); and said sheath comprises a hinge connecting said two half-round cross-sections together (Item 112).

22. A introducer comprising: a sheath made from a flexible plastic material (Item 100), said sheath comprising an outer surface and an inner surface (Item 100), said sheath further having a slot extending though a wall thereof and extending along an entire length of said sheath (Item 104), wherein said sheath is adapted to be inserted through

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a hemostatic valve, said outer surface thereby engaging and opening said hemostatic valve and said inner surface providing an open passageway through which a endovascular medical instrument is passed to minimize contact between said endovascular medical instrument and said hemostatic valve (functional language as stated above).

25. The introducer according to claim 22, wherein said inner surface of said sheath forms a substantially round cross-section in a free state (Fig 2).

26. The introducer according to claim 22, wherein said inner surface of said sheath forms two substantially half-round cross-sections in a free state, said two half-round cross-sections being connected to each other at one side and said two half-round cross-sections defining said slot at another side, said slot being open in said free state (Fig 1).

27. The introducer according to claim 22, wherein said sheath comprises a hinge connecting two adjacent portions of said sheath together (Item 112).

28. The introducer according to claim 27, wherein said hinge comprises a section of said sheath formed from a thinner cross-section of said flexible plastic material than said two adjacent portions (Item 112).

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29. The introducer according to claim 22, wherein a width of said slot is less than a diameter of said endovascular medical instrument (Fig 1).

30. The introducer according to claim 22, wherein a width of said slot is less than fifty percent of a diameter of said endovascular medical instrument (Fig 1).

32. The introducer according to claim 22, wherein said sheath comprises a hinge connecting two adjacent portions of said sheath together and a width of said slot is greater than a diameter of said endovascular medical instrument (Fig 2 Item 112, the slot will be greater than the width of the instrument so the instrument may be pressed into the slot).

37. The introducer according to claim 22, wherein said inner surface of said sheath forms two substantially half-round cross-sections in a free state, said two half-round cross-sections being connected to each other at one side and said two half-round cross-sections defining said slot at another side, said slot being open in said free state (Fig 1); and said sheath comprises a hinge connecting said two half-round cross-sections together (Item 112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-17, 19-30, 32-38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's disclosure in view of Stephens '586.

The Applicant has disclosed in Figures 1-8 labeled Prior Art a sheath (Item 30, 40, and 50) with a flange (Item 36 and 48) and beveled portion (Item 34) and a slot through the length of the sheath (Item 44). Embodiment 2 (Item 40) of the prior art is not made of a flexible material and is not hinged. Stephens teaches a flexible material for the sheath and a hinged portion (Col 2 Line 50 and Item 112). The flexible material and the hinge allow the sheath to easily receive the instrument and maintain a smaller diameter device. With embodiment 1 (Item 30) taken as the primary reference, the beveled portion (Item 34) and the flanged portion (Item 36) of the prior art is known but no slot is present. Again, Stephens teaches a flexible material for the sheath, a hinged portion, and a slot (Col 2 Line 50, Item 112, and 104). The flexible material, the hinge, and the slot allow the sheath to easily receive the instrument and maintain a smaller diameter device. The addition of a slot to facilitate the entry of the instrument into the sheath is also taught by embodiment 2 (Item 40). The combination of embodiment 1 (Item 30) and embodiment 2 (Item 40) would result in the slot being disposed at the heel of the bevel. The Examiner considers the placement of the slot at any desirable location to be within the purview of one having ordinary skill in the art. Locating the slot at the heel of the bevel would provide a leading tip that would reduce the likelihood of the sheath opening or peeling back upon entry into the valve. Therefore, it would have

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been obvious to a person having ordinary skill in the art at the time the invention was made to modify the prior art embodiments as disclosed by the Applicant to include the flexible material, slot, and hinge of Stephens. Such modifications would facilitate the placement of the instrument into the sheath.

Claims 10, 18, 31, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephens '586.

Stephens discloses the invention substantially as claimed as stated above. Stephens does not explicitly disclose the slot in the sheath being substantially closed in the free state. The Examiner considers substantially closing the slot (Item 104) to be within the purview of one having ordinary skill in the art. This modification would more securely hold the instrument in place during insertion. Furthermore, the Examiner is providing an example of a device for holding a catheter with both the open and closed configurations claimed to show that these configurations are within the purview of one having ordinary skill in the art. McIvor et al. (US 6,213,988) teaches a clip of similar cross section to the sheath containing a closed configuration (Fig 10A) and an open configuration (Fig 10B). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Stephens' slot to include a closed state. Such a modification provides the advantage of locking the device inside the sheath so that it will not be accidentally displaced during insertion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McIvor et al (US 6,213,988) was used as an example of a device

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with similar design characteristics that included both embodiments (open and closed) of the claimed invention. The reference was used as an example of what is within the purview of one having ordinary skill in the art, but not cited as a reference used in a rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


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11/4/07